

ANIMAX- nystatin, neomycin sulfate, thioestrepton and triamcinolone acetonide ointment
Dechra Veterinary Products

ANIMAX® OINTMENT
VETERINARY

nystatin-neomycin sulfate-thioestrepton-triamcinolone acetonide ointment

NADA# 140-847. Approved by FDA.

For use in dogs and cats only.

CAUTION:

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION:

Animax Ointment combines nystatin, neomycin sulfate, thioestrepton and triamcinolone acetonide in a non-irritating polyethylene and mineral oil base.

Each mL contains:

nystatin.....	100,000 units
neomycin sulfate equivalent to neomycin base.....	2.5 mg
thioestrepton	2,500 units
triamcinolone acetonide	1 mg

The preparation is intended for local therapy in a variety of cutaneous disorders of dogs and cats; it is especially useful in disorders caused, complicated, or threatened by bacterial and/or candidal (monilial) infection.

ACTIONS:

By virtue of its four active ingredients, Animax Ointment provides four basic therapeutic effects: anti-inflammatory, antipruritic, antifungal and antibacterial. Triamcinolone acetonide is a potent synthetic corticosteroid providing rapid and prolonged symptomatic relief on topical administration. Inflammation, edema, and pruritis promptly subside, and lesions are permitted to heal. Nystatin is the first well-tolerated antifungal antibiotic of dependable efficacy for the treatment of cutaneous infections caused by *Candida albicans* (Monilia). Nystatin is fungistatic *in vitro* against a variety of yeast and yeast-like fungi including many fungi pathogenic to animals. No appreciable activity is exhibited against bacteria. Thioestrepton has a high order of activity against gram-positive organisms, including many which are resistant to other antibiotics; neomycin exerts antimicrobial action against a wide range of gram-positive and gram-negative bacteria. Together they provide comprehensive therapy against those organisms responsible for most superficial bacterial infections.

WARNINGS:

Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

Additionally, corticosteroids administered to dogs, rabbits and rodents during pregnancy have resulted in cleft palate in the offspring. In dogs, other congenital anomalies have resulted: deformed forelegs,

phocomelia, and anasarca.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

INDICATIONS:

Animax Ointment is particularly useful in the treatment of acute and chronic otitis of varied etiologies, in interdigital cysts in cats and dogs and in anal gland infections in dogs.

The preparation is also indicated in the management of dermatologic disorders characterized by inflammation and dry or exudative dermatitis, particularly those caused, complicated, or threatened by bacterial or candidal (*Candida albicans*) infections. It is also of value in eczematous dermatitis, contact dermatitis, and seborrheic dermatitis; and as an adjunct in the treatment of dermatitis due to parasitic infestation.

PRECAUTIONS:

Animax Ointment is not intended for the treatment of deep abscesses or deep-seated infections such as inflammation of the lymphatic vessels. Parenteral antibiotic therapy is indicated in these infections.

Animax Ointment (Nystatin-Neomycin Sulfate-Thiostrepton-Triamcinolone Acetonide Ointment) has been extremely well tolerated. Cutaneous reactions attributable to its use have been extremely rare. The occurrence of systemic reactions is rarely a problem with topical administration. There is some evidence that corticosteroids can be absorbed after topical application and cause systemic effects. Therefore, an animal receiving Animax Ointment therapy should be observed closely for signs such as polydipsia, polyuria, and increased weight gain.

Animax Ointment is not generally recommended for the treatment of deep or puncture wounds or serious burns.

Sensitivity to neomycin may occur. If redness, irritation, or swelling persists or increases, discontinue use. Do not use if pus is present since the drug may allow the infection to spread.

Avoid ingestion. Oral or parenteral use of corticosteroids (depending on dose, duration of use, and specific steroid) may result in inhibition of endogenous steroid production following drug withdrawal.

SIDE EFFECTS:

SAP and SGPT (ALT) enzyme elevations, polydipsia and polyuria, vomiting, and diarrhea (occasionally bloody) have been observed following parenteral or systemic use of synthetic corticosteroids in dogs.

Cushing's syndrome has been reported in association with prolonged or repeated steroid therapy in dogs. Temporary hearing loss has been reported in conjunction with treatment of otitis with products containing corticosteroids. However, regression usually occurred following withdrawal of the drug. Hearing loss, with varying degrees of recovery, has been reported with the use of Animax Ointment. If hearing dysfunction is noted during the course of treatment with Animax Ointment, discontinue its use.

CAUTION:

Before instilling any medication into the ear, examine the external ear canal thoroughly to be certain the tympanic membrane is not ruptured in order to avoid the possibility of transmitting infection to the middle ear as well as damaging the cochlea or vestibular apparatus from prolonged contact. If hearing or vestibular dysfunction is noted during the course of treatment, discontinue the use of Animax Ointment.

DOSAGE AND ADMINISTRATION:

Frequency of administration is dependent on the severity of the condition. For mild inflammations, application may range from once daily to once a week; for severe conditions Animax Ointment may be applied as often as two to three times daily, if necessary.

Frequency of treatment may be decreased as improvement occurs.

Wear gloves during the administration of the ointment or wash hands immediately after application.

Otitis

Clean ear canal of impacted cerumen. Inspect canal and remove any foreign bodies such as grass awns, ticks, etc. Instill three to five drops of Animax Ointment.

Preliminary use of a local anesthetic may be advisable.

Infected Anal Glands, Cystic Areas, etc.

Drain gland or cyst and then fill with Animax Ointment.

Other Dermatologic Disorders

Clean affected areas, removing any encrusted discharge or exudate. Apply Animax Ointment (Nystatin-Neomycin Sulfate-Thiostrepton-Triamcinolone Acetonide Ointment) sparingly in a thin film.

HOW SUPPLIED:

Animax Ointment is supplied in tubes as follows:

7.5 mL tubes NDC 17033-122-75

15 mL tubes NDC 17033-122-15

30 mL tubes NDC 17033-122-30

240 mL bottles NDC 17033-122-24

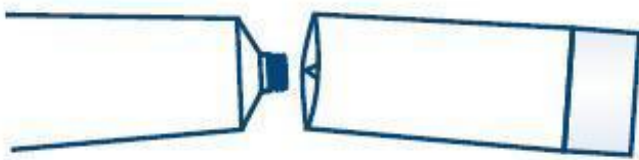
STORAGE:

Store at room temperature; avoid excessive heat (104°F).

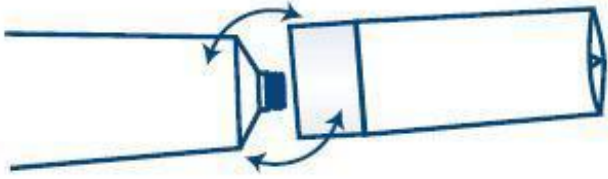
240 mL bottle: Do not store above 86°F.

TO OPEN:

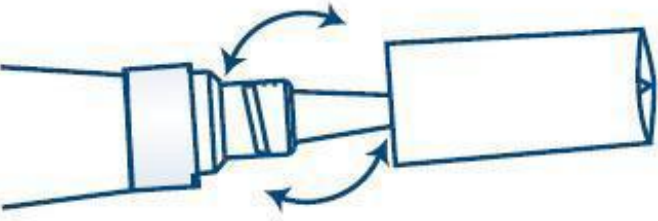
Use cap to puncture seal.



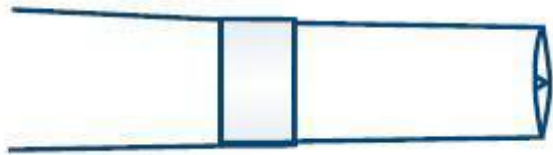
1. Remove entire Applicator Assembly, puncture tube with white portion of the cap.



2. Replace entire Applicator Assembly.



3. To dispense, remove the white portion of the cap.



4. After use replace white cap to close.

IMPORTANT:

The opening of this product is covered by a metal tamper-resistant seal.

If this seal has been punctured or is not visible, do not use and return product to place of purchase.

MANUFACTURED FOR:

Dechra Veterinary Products, Overland Park, KS 66211

MANUFACTURED BY:

Fougera Pharmaceuticals Inc., Melville, NY 11747 USA

400136A/400137A R02/13 #566

PRINCIPAL DISPLAY PANEL - 7.5 mL Carton

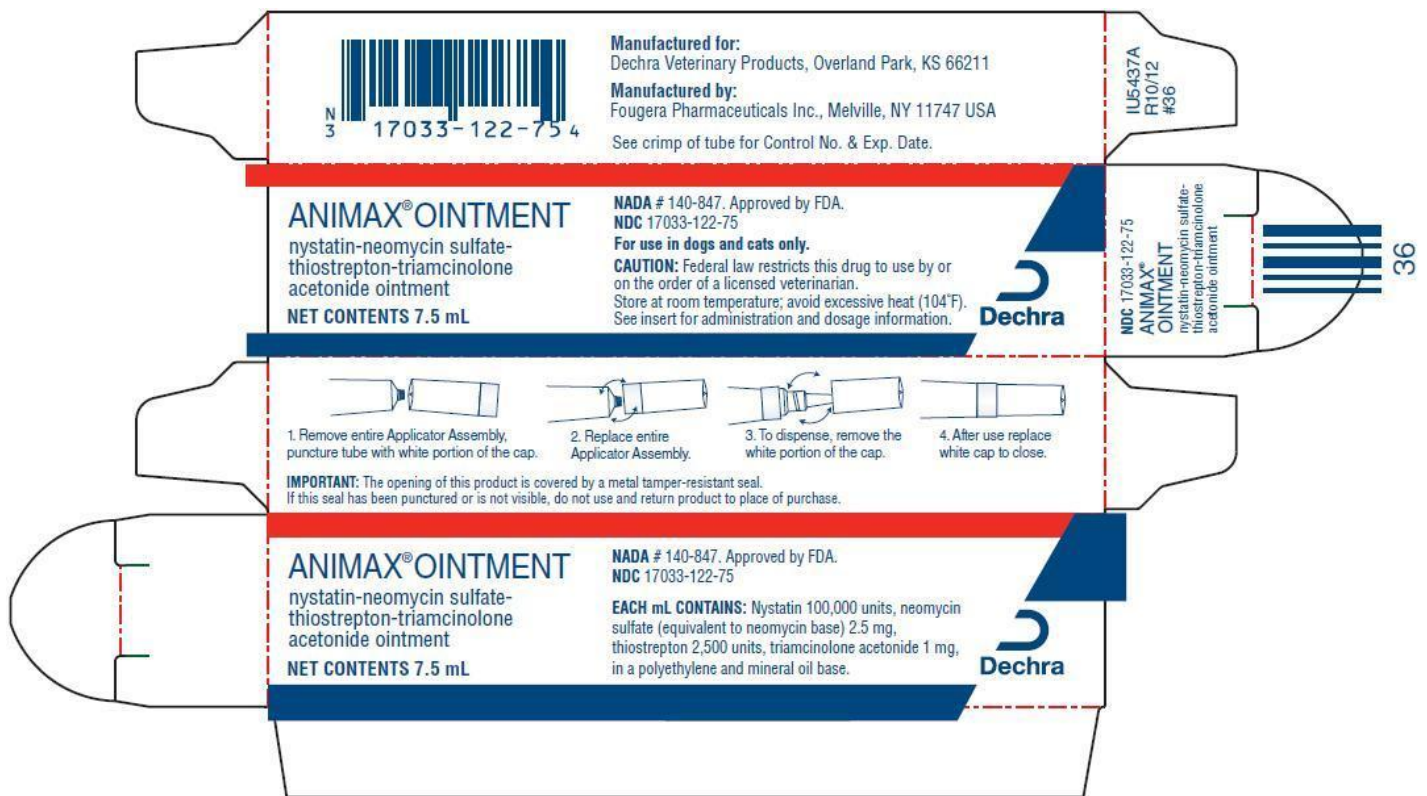
ANIMAX[®] OINTMENT

nystatin-neomycin sulfate-thiostrepton-triamcinolone acetone ointment

NET CONTENTS 7.5 mL

NADA # 140-847. Approved by FDA

NDC 17033-122-75



PRINCIPAL DISPLAY PANEL - 7.5 mL Container

NET CONTENTS 7.5 mL

NDC 17033-122-75

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Product Information				
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:17033-122	
Route of Administration	TOPICAL, AURICULAR (OTIC)	DEA Schedule		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
NYSTATIN (UNII: BDF1O1C72E) (NYSTATIN - UNII:BDF1O1C72E)		NYSTATIN	100000 [USP'U] in 1 mL	
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)		NEOMYCIN	2.5 mg in 1 mL	
THIOSTREPTON (UNII: HR4S203Y18) (THIOSTREPTON - UNII:HR4S203Y18)		THIOSTREPTON	2500 [USP'U] in 1 mL	
TRIAMCINOLONE ACETONIDE (UNII: F446C597KA) (TRIAMCINOLONE ACETONIDE - UNII:F446C597KA)		TRIAMCINOLONE ACETONIDE	1 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)				
MINERAL OIL (UNII: T5L8T28FGP)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17033-122-75	1 in 1 CARTON		
1		7.5 mL in 1 TUBE		
2	NDC:17033-122-15	1 in 1 CARTON		
2		15 mL in 1 TUBE		
3	NDC:17033-122-30	1 in 1 CARTON		
3		30 mL in 1 TUBE		
4	NDC:17033-122-24	1 in 1 CARTON		
4		240 mL in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA140847	09/30/1988		

Labeler - Dechra Veterinary Products (362142734)

Registrant - Fougera Pharmaceuticals Inc. (043838424)